

Appl. No. 10/792,076
Amdt. dated March 14, 2006
Reply to Office Action of December 14, 2005

REMARKS

Applicants have carefully reviewed the Office Action of December 14, 2005 and submit the following comments in response thereto. Claims 1-44 are pending, wherein claims 5, 12-16, 20-27, 30, 36 and 40-44 are withdrawn from consideration; claims 1-4, 6, 8-11, 17-19, 28-29, 31, 34-35 and 37 are rejected, and claims 7, 32, 33 and 38-39 are objected to.

Election/Restriction Requirement

Applicants hereby affirm the telephonic election of Species I without traverse. Species I corresponds to claims 1-4, 6-11, 17-19, 28-29, 32-35 and 37-39.

Claim Amendments

Claim 1 has been amended to delete the phrase "to the first diameter" and to incorporate the elements of claim 6. (Claim 6 has been cancelled.)

Claim 28 has been amended to incorporate the elements of claims 29 and 31 (which have been cancelled).

Claim 34 has been amended to incorporate the elements of claim 37 (which has been cancelled)

No new or unelected matter has been introduced.

Claim Rejections—35 U.S.C. § 102

Claims 1-4, 6, 8-9, 17, 28-29, 31 and 34-35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Roberts et al. (U.S. Pat. No. 5,545,209). Applicants respectfully traverse the rejection.

Roberts et al. disclose a balloon catheter system where a constraint is disposed partially over the balloon to radially constrain part of the balloon. The constraint may be a sheath designed to axially slide along a length of the balloon in response to a pressure in the balloon so

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that the balloon may be progressively incrementally inflated or may be a band around the balloon.

Applicants submit that Roberts et al. do not disclose a catheter "wherein the proximal portion of the balloon is releasably attached to the shaft" as is recited in amended independent claim 1.

In the Office Action it is written that "the balloon proximal portion is releasably attached to the shaft by epoxy adhesive. The term 'releasably' or 'releasable' is considered to be intended use." Two different propositions are being advanced in these two sentences. First, that Roberts et al. disclose a balloon proximal portion releasably attached to the shaft by epoxy adhesive. And second, that the term "releasably" is not an element that gives any structure to the claim. Applicants respectfully disagree with both statements.

As to the first proposition, Roberts et al. do disclose attaching the balloon sleeves 16 to the catheter by epoxy. However, Roberts et al. do not disclose this to be a releasable attachment. A releasable attachment as used in this specification means that the attachment will release when the balloon is filled with sufficient pressure. See generally the paragraph at page 11, line 16. All attachments and even all epoxy attachments are not releasable attachments. Consider the case of a balloon catheter where the epoxy and the bond formed by the epoxy is stronger than the material of the balloon. When one inflates such a balloon catheter past a certain point, the balloon will rupture, while the bond and the epoxy remain unaffected. It is thus easy to see that all attachments are not releasable attachments and that merely because Roberts et al disclose an epoxy attachment, they do not inherently disclose a releasable attachment between the balloon and the catheter.

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As to the second proposition, namely that the term "releasably" is not entitled to patentable weight, "releasably" is a term which modifies "attached" in a manner that avoids undue breadth or vagueness. Catheters wherein the proximal portion of the balloon is releasably attached to the shaft is a subset of the group of catheters wherein a balloon is attached to the shaft. Applicants respectfully assert that the definition attributed to a claim term must "be consistent with the interpretation that those skilled in the art would reach." See M.P.E.P. §2111, citing *In re Cortright*, 165 F.3d 1353, 1359. No one of skill in the art would construe the term "releasably" to be a statement of intended use and accord it no structural weight; on the contrary, those of skill in the art would interpret the term "releasably" in a manner consistent with this discussion.

Because the term "releasably attached" is due appropriate patentable weight and because Roberts et al. do not disclose a catheter wherein the balloon is releasably attached to the catheter shaft, applicants submit that claim 1 is allowable. Applicants also submit that claims 2-4, 8-9 and 17, which depend from claim 1 and contain additional elements are also in condition for allowance.

Claim 28 recites "a catheter assembly comprising...an expandable balloon disposed about the distal region of the shaft...wherein the second portion of the balloon is releasably attached to the shaft."

As discussed above, the phrase "releasably attached" is due patentable weight and Roberts et al. do not disclose a catheter assembly where a portion of the balloon is releasably attached to the shaft. Applicants therefore submit that claim 28 is in condition for allowance.

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Claim 34 recites "a balloon catheter comprising...an inflatable balloon...having a first longitudinal portion and a second longitudinal portion and distal and proximal ends...wherein the second longitudinal portion of the balloon is releasably attached to the shaft."

For the reasons discussed above, Applicants submit that claim 34 is in condition for allowance. As claim 35 depends from claim 34 and contain additional elements, Applicants submit that this claim is also in condition for allowance.

Claims 1-4, 6, 9, 28-29, 34-35 and 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by Briscoe et al. (U.S. Patent No. 6,458,096). Applicants respectfully traverse the rejection.

Briscoe et al. disclose a balloon catheter having an auto-regulating structure to prevent overinflation of the balloon. The auto-regulating structure is a tight-fitting distal end that discharges more fluid as the balloon is inflated.

As Briscoe et al. disclose, "the first embodiment of the autoinflation, autoregulating balloon according to the invention incorporates an expandable member such as a tightly fitting, elastomeric balloon 46 telescopically received on the distal end 18 of the catheter 14...The proximal end of the balloon 46 is secured to the outside surface of the catheter 14 by an adhesive or other convention means to create a proximal retention collar 48. However, the distal end 50 of the balloon 46 is not secured to the outside surface of the catheter 14." Column 5, lines 9-24.

In contrast, claim 1 recites "wherein the proximal portion of the balloon is releasably attached to the shaft."

The conventional means used to secure the balloon of Briscoe et al. at the proximal end is not, as the discussion above with regard to Roberts et al., a releasable attachment. With regard to the distal end of the balloon of Roscoe et al., at least two points of distinction are evident. First,

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the distal end is not attached, and second, it is at the distal end of the balloon and consequently has nothing to do with the attachment of the proximal portion of the balloon to the shaft.

For at least these reasons, Applicants submit that claim 1 is in condition for allowance. As claims 2-4, and 9 depend from claim 1 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 28 recites "a catheter assembly comprising...an expandable balloon disposed about the distal region of the shaft...wherein the second portion of the balloon is releasably attached to the shaft."

As this claim contains no elements concerning where (i.e., proximal, distal, etc.) the second portion is attached, it is worth elaborating on the point that the distal end of the catheter of Roscoe et al. is not attached. As Roscoe et al. state, "the distal end 50 of the balloon 46 is not secured to the outside surface of the catheter 14. In the relaxed state, the distal end 50 of the balloon 46 tightly surrounds the catheter." Column 5, lines 23-26. The example that perhaps most readily illustrates that attachment between the balloon and the catheter is not inherent at the distal end even though the balloon tightly surrounds the catheter is that of the clown filling helium balloons. When a clown fills a helium balloon he holds the neck of the balloon over a nozzle. Two things are apparent. First, that unless the neck of the balloon tightly surrounds the nozzle, the balloon is not going to get filled. And second, unless the clown is holding the balloon onto the nozzle, the balloon will fly off—in other words, the balloon is not attached. Likewise, in the catheter of Briscoe et al., the only attachment that secures the balloon to the catheter is the proximal retention collar 48. The mere fact that the distal end of the balloon is tightly surrounding the catheter does not tell us whether the distal end of the balloon is attached

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to the collar. Briscoe et al. do not disclose a portion of the balloon releasably attached to the catheter shaft.

For at least these reasons, Applicants submit that claim 28 is in condition for allowance.

Claim 34 recites “a balloon catheter comprising...an inflatable balloon...having a first longitudinal portion and a second longitudinal portion and distal and proximal ends...wherein the second longitudinal portion of the balloon is releasably attached to the shaft.”

For the reasons discussed above with respect to claim 28, Applicants submit that claim 34 is in condition for allowance. As claim 35 depends from claim 34 and contains additional elements, Applicants submit that this claim is in condition for allowance.

Claims 1-2, 28-29 and 34-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by Musbach et al. (U.S. Patent No. 6,835,189). Applicants respectfully traverse this rejection.

Independent claim 1 has been amended to incorporate the elements of claim 6, independent claim 28 has been amended to incorporate the elements of claim 31, and independent claim 34 has been amended to incorporate the elements of claim 37. Claims 6, 31 and 37 were not rejected against this piece of art. Applicants respectfully submit that, consequently, claims 1, 28 and 34 are allowable. As claims 2 and 35 each depend from one of these claims and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim Rejections—35 U.S.C. § 103

Claims 10-11 and 18-19 were rejected under 35 U.S.C. § 103(a). As these claims depend from claim 1 (which is in condition for allowance) and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

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Claim Objections

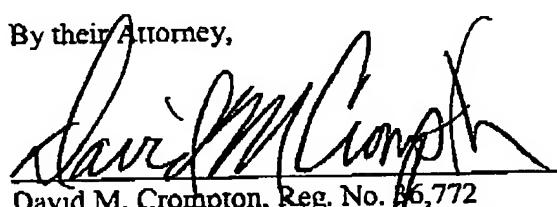
Claims 7, 32, 33, 38 and 39 were objected to as being dependent on a rejected base claim, but are otherwise indicated allowable. As these claims currently depend from claims that Applicants submit are allowable, Applicants respectfully request the withdrawal of the objection.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Elaine Lim et al.

By their Attorney,



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